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Display Date 4-9-02
Publication Date 4-10-02
Certifier A. Corbin

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Information Association and Food and Drug Administration on the Fourth Project Management Workshop: Effective Agency/Industry Interactions to Expedite Drug Development; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) in cosponsorship with the Drug Information Association (DIA) is announcing a public workshop entitled "The Fourth Project Management Workshop: Effective Agency/Industry Interactions to Expedite Drug Development." The workshop will focus on facilitating drug development and drug review processes.

Date and Time: The workshop will be held on April 30, 2002, from 8:30 a.m. to 5 p.m., May 1, 2002, from 8:30 a.m. to 5 p.m., and May 2, 2002, from 8:30 a.m. to 12:30 p.m.

Location: The workshop will be at the Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD.

Contacts: For information about this notice: Michael D. Anderson, Center for Biologics Evaluation and Research (CBER) (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6210, FAX 301–594–1944, e-mail: Andersonm@cber.fda.gov.

For information about the workshop: David Roeder, Center for Drug Evaluation and Research (CDER) (HFD-104), Food and Drug Administration, 9201 Corporate Blvd. Rockville, MD 20850, 301–827–2488, FAX 301–827–2520, e-mail: Roederd@cder.fda.gov, or Gail Sherman, Center for Biologics Evaluation and Research (HFM–42), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–2000, FAX 301–827–3079, e-mail: Sherman@cber.fda.gov, or Camela Pastorius, Drug Information Association (DIA), 501 Office Center Dr., suite 450, Fort

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Washington, PA 19034, 215–591–3303, FAX 215–641–1229, e-mail: Camela.Pastorius@diahome.org. If you need special accommodations due to a disability, please contact Camela Pastorius (address above) by April 23, 2002.

Registration: Mail or fax your registration information and registration fee to DIA, P.O. Box 7777–W8405, Philadelphia, PA 19175. You may obtain registration forms from DIA (see contact information) or from FDA at http://www.fda/gov/cber/meetings.htm. Additional information regarding registration fees and online registration can be found at http:/www.diahome.org/docs/Events/Events—search—detail.cfm?EventID=0201.

SUPPLEMENTARY INFORMATION: FDA (CBER and CDER) and DIA are cosponsoring a workshop as part of a continuing effort to develop higher levels of teamwork, communication, and procedural knowledge to facilitate drug development and review in the United States. The workshop's target audience is FDA regulatory project managers and pharmaceutical industry project management and regulatory teams who have mid-level experience and are involved in daily agency-industry interactions.

The workshop will present three major themes:

• Planning and Teamwork—attendees will participate in activities designed to highlight the value of teamwork, and to exchange ideas about team organization and management;

• Understanding the Process of Regulatory Project Management—the workshop will explore parallel objectives and activities within industry and FDA and identify opportunities for effective interaction. Attendees will also share ideas for optimizing working relationships between project management and regulatory professionals and between industry representatives and FDA regulatory project managers;

• Key Factors for Success—the workshop will present a set of experience-based factors for successful FDA/industry interaction.

Dated: 4/4/02
April 4, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

BILLING CODE 4160–01–S